

Remarks

The Amendments

Claim 1 has been amended to clarify that a chromatography region is associated with the detection member. This is not a narrowing amendment. The amendment is merely made to clarify the claimed subject matter. The amendment is supported by the specification at, *inter alia*, page 18, lines 5 through 9 and Figures 2 and 3.

Claim 1 has been amended to recite “having” instead of “with” according to the Office’s suggestion. This is not a narrowing amendment. The amendment merely clarifies the claim language.

Claim 1 has been amended to recite:

a reagent delivery system positioned relative to the sampler member for delivery a liquid reagent to the sample collector, wherein the reagent delivery system is positioned so that the liquid reagent is added to the reagent delivery system after the sampler member and detection member are assembled into one part and flows through the sample collector and into the chromatography region.

Support for the amendment can be found in the specification at, *inter alia*, page 12, line 16 through page 13, line 2; page 15, lines 13-19; Example 1.

Claim 7 has been amended to recite that the reagent delivery system comprises an absorbent reagent pad. Support for the amendment can be found in the specification at, *inter alia* page 23, lines 12-13. This is not a narrowing amendment.

These amendments add no new matter and Applicants respectfully request their entry.

Formal Drawings

Applicants have attached formal drawings. The drawings add no new matter and Applicants respectfully request their entry.

Rejection of Claims 1-33 Under 35 U.S.C. §112, second paragraph

Claims 1-33 stand rejected under 35 U.S.C. §112, second paragraph as allegedly lacking definiteness. Applicants respectfully traverse the rejection.

To ascertain whether a claim lacks definiteness a determination is required of whether those skilled in the art would understand what is claimed when the claim is read in light of the specification. *Seattle Box Co. v. Industrial Crating & Packing Inc.*, 221 USPQ 568, 574 (Fed. Cir. 1984); *In re Morasi*, 218 USPQ 289, 292 (Fed. Cir. 1983).

The Office Action asserts that claim 1 fails to specifically set forth the invention as disclosed in the specification because a device comprising a sampler member and a detection member that can be separated into two parts and assembled into one part by insertion of the sampler component into the detection component is not specifically claimed. The Office Action also asserts that it is unclear where the chromatography region is located.

Initially, claim 1 has been amended to recite that the chromatography region is associated with the detection member. The claim further recites that chromatography region comprises a chromatography medium having a transit zone and a capture zone. The claim goes on to recite that the sample collector is in capillary communicating contact with the capture zone through the transit zone when the device is assembled.

Additionally, the specification provides several exemplary drawings of the claimed devices that demonstrate placement of the chromatography region. See e.g., Figures 1-7. Therefore, claim 1 is clear as to the location of the chromatography region.

Furthermore, claim 1 clearly recites that the device comprises “a sampler member and a detection member”, “wherein the device is capable of being separated into at least two parts comprising the sampler member and the detection member, and the device is further capable of being assembled into one part.” Claim 1 also states that a sample collector is associated with the sampler member and that a chromatography region is associated with the detection member and comprises a transit zone and a capture zone and that when the device is assembled the sample collector associated with the sampler member is in capillary communicating contact with the capture zone through the transit zone. The specification also provides several exemplary drawings of the claimed devices that demonstrate the sampler member and the detection member. See e.g., Figures 1-7.

Therefore, one of skill in the art would understand what is claimed when the claim is read in light of the specification, including how the sampler member and the detection member can be separated into two parts and assembled into one part.

Applicants respectfully request withdrawal of the rejection.

Rejection of Claims 1-4, 6-9, 14-28, 31 and 32 Under 35 U.S.C. §102(e)

Claims 1-4, 6-9, 14-28, 31 and 32 stand rejected under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Pat. No. 5,877,028 (the ‘028 patent). Applicants respectfully traverse the rejection.

Anticipation under 35 U.S.C. § 102 requires the presence in a single prior art disclosure of each and every element of a claimed invention. *Lewmar Marine Inc. v. Barient Inc.*, 3 USPQ2d 1766, 1767 (Fed. Cir. 1987).

The Office Action asserts that the '028 patent discloses the device of the instant invention. However, the '028 patent does not teach or suggest a device with a reagent delivery system in addition to a sample collector wherein the reagent delivery system is positioned relative to the sampler member for delivery a liquid reagent to the sample collector. Furthermore, the '028 patent does not teach or suggest a device with a reagent delivery system that is positioned so that the liquid reagent is added to the reagent delivery system after the sampler member and detection member are assembled into one part and flows through the sample collector and into the chromatography region. Therefore, the '028 does not anticipate the present invention because it does not teach or suggest each and every element of the claimed invention. Applicants respectfully request withdrawal of the rejection.

Respectfully submitted,
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Dated: _____

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